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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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1. This is a continuation-in-part of U.S. Patent No. 4,123,456, filed 1/1/77, and is hereby incorporated by reference.

EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/726,093

Applicant(s)

Fuchs et al.

Examiner

Ardin Marschel

Group Art Unit

1631



☒ Responsive to communication(s) filed on Feb 23, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 54, 57-62, and 64-71 is/are pending in the application

~~on file above, Claim(s) 1-53, 55, 56, 63, and 72-74 have been canceled.~~ ~~is/are withdrawn from consideration~~

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 54, 57-62, and 64-71 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Due to reconsideration of the instant application, newly applied rejections are herein summarized below. Due to the application of these new rejections, the finality of the office action, mailed 11/23/99, is hereby withdrawn.

Applicants' arguments, filed 2/23/00, have been fully considered and they have been found to be persuasive to overcome previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 57-60, 64, 65, and 67-71 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fuchs et al. (P/N 5,630,924).

Various probes or binding partners are described which are utilized in the detection practice of the reference as described in column 8, lines 45-67. At least a portion of these probes may be made up of PNA which qualifies as a PNA probe due to the description in column 10, lines 52-62. The generic practice of binding partners is motivated and suggested in the last 2 lines in column 8 via the phrase "preferred binding partners are those suitable for detection of clinically significant analytes". These binding partners are detectably labeled as noted in column 9, lines 1-55. An apparatus is described in column 15, lines 2-36, wherein complex formation occurs either in "pre-formed zones" such that complex formation can occur prior to separation in a sample introduction zone. Detection of the entities after separation is also described. The medium that is utilized in the reference in the separation zone is summarized in column 16, lines 15-32, to include sieving medium material as also given in instant claim 59. Specific examples of media are described in column 18, lines 29-51, such as also given in instant claim 60.

Microchips may be utilized for the apparatus as given in column 20, lines 4-48.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice a specie of the various probes and apparatus of the reference as described above.

Claims 54, 57, 58, 61, 62, and 65-68 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dolan et al. (P/N 5,985,153) in view of Summerton et al. (P/N 5,217,866).

Dolan et al. describes magnetic separation apparatus as given in Figure 5A wherein a sample is introduced at one end and is magnetically separated in the channel depicted in Figure 5B. Peptide nucleic acids with magnetic particles attached are suggested and motivated as specific binding substances as given in column 8, lines 23-67.

Summerton et al. taken as a whole describes PNA probes as desirable alternatives to DNA probes as specific binding partners including labeling with detectable moieties. Summerton et al. in column 21, line 13, through column 24, line 38, describes hybridization conditions with specific denaturants such as formamide and low ionic conditions described in column 22, lines 41-50, as also required in instant claims 61 and 62.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice a specie of the various probes and apparatus of the reference as described above.

Claims 57-62, 64, 65, and 67-71 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fuchs et al. (P/N 5,630,924) taken in view of Summerton et al. (P/N 5,217,866).

The Fuchs et al. description of the invention has been described above but lacks formulations for hybridization between targets and PNA probes but suggests such hybridization under appropriate conditions.

Summerton et al. in column 21, line 13, through column 24, line 38, describes hybridization conditions with specific denaturants such as formamide and low ionic conditions described in column 22, lines 41-50, as also required in instant claims 61 and 62.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice a specie of the various probes and apparatus of the reference as described above.

No claim is allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)305-3014 or (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be

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reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

March 17, 2000

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER